IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

ROY WILMOTH, JR. **PLAINTIFF**

v. **CIVIL ACTION NO. 3:20-cv-120-NBB-RP**

ALEX M. AZAR, II, in his official capacity as Secretary of the U.S. Department of Health and Human Services **DEFENDANT**

DEFENDANT'S MEMORANDUM IN OPPOSITION TO PLAINTIF'S MOTION FOR SUMMARY JUDGMENT

Defendant Alex M. Azar II, the Secretary of Health and Human Services, (Secretary), opposes Plaintiff's Motion for Summary Judgment, as follows:

Introduction

This case involves judicial review of the denial of Medicare claims by the Medicare Appeals Council for certain months of the Optune device that provided tumor treatment field therapy (TTFT) to the Plaintiff. The decision denying Plaintiff's claims, however, concluded that the device manufacturer would be liable for payment of the non-covered charges - not the Plaintiff.

Plaintiff raises a single issue on appeal: whether the Secretary is collaterally estopped from denying his claims for the TTFT device because certain ALJs allowed coverage for different months of the TTFT device, in earlier non-precedential decisions.[1] The resolution of this issue is clear: collateral estoppel does not apply. In arguing that a non-precedential ALJ decision estops the Secretary from denying Plaintiff's claim for the TTFT device, Plaintiff relies on *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), which held that administrative decisions can have preclusive effect

[1] By omission, Plaintiff waived his right to challenge the ALJ decision at issue on the other grounds listed in his Complaint. *United States v. Whitfield*, 590 F.3d 325 (5th Cir. 2009) (party generally waives any argument that it fails to brief on appeal).

when there is not an evident statutory purpose to the contrary. *Id.* at 108. In the context of ALJ decisions in Medicare claim appeals, however, there is a statutory purpose to the contrary, as evidenced by the Medicare Act's: (1) requirement that ALJ decisions receive *de novo* review, (2) allowance for the Secretary to resolve claim appeals through individual adjudications, (3) requirement that claims for benefits be presented and channeled through administrative review, and (4) authorized regulations, which foreclose giving preclusive effect to ALJ decisions by specifying that such decisions are not precedential or final. Even if there were no bar to collateral estoppel, Plaintiff would not be entitled to collateral estoppel in this case because the required elements are not met. In particular, notwithstanding that ALJ decisions in the Medicare claim appeals context are not "final" for purposes of collateral estoppel, the issue at stake is not identical to the one involved in the earlier proceedings, the issue was not actually litigated in the earlier proceedings, and the Secretary did not have a full and fair opportunity to litigate in the earlier proceedings because it would be impracticable for the Secretary to appear as a party in the thousands of Medicare claim appeals that are filed each year at the ALJ level. For all these reasons, plaintiff's motion for summary judgment should be denied.

Argument

A. The Secretary Is Not Collaterally Estopped From Denying Plaintiff's Claim

Plaintiff's motion for summary judgement should be denied because Plaintiff's sole argument on appeal—that an earlier favorable ALJ decision estops the Secretary from denying coverage—is inconsistent with the law, applicable regulations, and the Medicare Act. First, ALJ decisions on Medicare claim appeals are not entitled to preclusive effect. And second, the elements of collateral estoppel are not met.

Under *Astoria Federal Savings and Loan Association v. Solimino*, 501 U.S. 104 (1991), the presumption that decisions issued by administrative agencies may have preclusive effect is overcome "when a statutory purpose to the contrary is evident." *Id.* at 108. A statutory purpose to the contrary may be evidenced either expressly or implicitly. *Id.* at 108-110.[2] As discussed in the Secretary's principal brief, in the context of ALJ decisions in Medicare claim appeals a statutory purpose to the contrary is evidenced in several ways. Docket 58, pp. 8-16.

First, the Medicare Act requires the Council to review ALJ decisions *de novo*. 42 U.S.C. § 1395ff(d)(2)(B). If a favorable ALJ ruling collaterally estopped the Council from denying a beneficiary's claim for the same treatment, then the Council could not perform a *de novo* review; instead, the Council would be bound to accept the conclusions of an ALJ, a lower-level adjudicator. *Almy v. Sebelius*, 679 F.3d 297, 310 (4th Cir. 2012) (Council's requirement to perform *de novo* review is incompatible with prospect of deferring to outcomes of ALJ decisions below).

Second, the Secretary has discretion under the Medicare Act to implement the "reasonable and necessary" standard through individual claim adjudications. *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 97 (1995) ("The Secretary's mode of determining benefits by both rulemaking and adjudication is, in our view, a proper exercise of her statutory mandate."). Under Plaintiff's theory, once one

[2] Plaintiff's citation to *U.S. v. Texas*, 507 U.S. 529, 534 (1993), for the proposition that a statute must speak directly to the question addressed by the common law is inapposite because that case, unlike *Astoria*, did not specifically address collateral estoppel. Docket 60, p. 5. Additionally, the *Texas* court in fact endorsed Congress' ability to implicitly evidence a statutory purpose to the contrary of a common law principle, stating "[w]e agree with Texas that Congress need not affirmatively proscribe the common-law doctrine at issue." *Id.* (internal quotation omitted).

ALJ has approved a claim for benefits, future ALJs and the Medicare Appeals Council would not be permitted to reach the opposite conclusion, depriving them of the ability to individually adjudicate the claim before them.[3] Plaintiff's interpretation would render the Medicare Appeals Council superfluous because the Council would be bound by lower level ALJ decisions.

Third, the Medicare Act requires that all claims for benefits be presented and channeled through administrative review. *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000) (citing *Ringer*, 461 U.S. at 614). If the Secretary were collaterally estopped from denying Plaintiff's claims for the Optune device, then Plaintiff would be establishing an entitlement to future Medicare benefits for the Optune device even though claims for those benefits have not yet been presented or channeled.[4] *Porzecanski v. Azar*, 943 F.3d 472, 482-83 (D.C. Cir. 2019) (rejecting plaintiff's request for prospective relief mandating that the Secretary recognize his treatment as a covered Medicare benefit in all future claim determinations, because this would violate the presentment and channeling requirement).

Finally, the Medicare Act confers the Secretary with broad authority to promulgate regulations, 42 U.S.C. §§ 1395ff(a)(1), 1395hh, and these regulations foreclose the possibility that ALJ decisions in the Medicare claim appeals context can have any preclusive effect. In particular, the regulations specify that only Council-level decisions

[3] Plaintiff articulates no reason, should ALJ decisions be entitled to preclusive effect, why the first *denial* of benefits should not correspondingly estop the beneficiary from making future attempts to secure Medicare coverage. The absurdity of this outcome further illustrates that the Medicare Act's allowance for individual adjudications is incompatible with giving preclusive effect to ALJ decisions.

[4] Plaintiff explicitly requests a finding that the Secretary is collaterally estopped from denying his Medicare claim, and all future claims for TTFT, as opposed to a finding that the ALJ's decision was unsupported by substantial evidence, in order to circumvent future participation in the Medicare claim appeals process. Docket 60, p. 1.

have the potential to become precedential (*i.e.*, binding in future cases). 42 C.F.R. § 401.109; 42 C.F.R. §§ 405.968(b) (omitting ALJ decisions from rulings that bind the QIC), 405.1062(b) (ALJ decisions that depart from LCDs apply only to the specific claim being considered and have no precedential effect). If an ALJ decision has no precedential effect and is not binding on future parties, then it cannot have preclusive effect for purposes of collateral estoppel. *Christenson v. Azar*, No. 20-cv-194, 2020 WL 3642315, at *6 (E.D. Wis. Jul. 6, 2020), *appeal docketed*, No. 20-3070 (7th Cir. Oct. 22, 2020) ("If a decision is deemed not to have 'precedential effect' on the *same* parties in the future, it necessarily forecloses when and where collateral estoppel can apply.")(emphasis in original).[5]

The Medicare regulations further indicate that ALJ decisions do not constitute the "final" decision of the Secretary. *Cf.* 42 C.F.R. §§ 405.1130 (Council's decision is "*final* and binding on all parties")(emphasis added), 405.1048 (ALJ's decision is "binding on all parties"). The Secretary's determination that ALJ decisions are not "final" is conclusive for purposes of collateral estoppel. Restatement (Second) of Judgments § 13 (1982)[6] ("final judgment" for purposes of collateral estoppel means "any prior adjudication of an issue in another action *that is determined to be sufficiently firm to be accorded conclusive effect.*") (emphasis added); *Christenson*, 2020 WL 3642315, at *6 ("In the administrative realm, it is not unreasonable or arbitrary for the Secretary to decide what stage deserves preclusive effect."); *see also*, *id.* ("It is difficult to conclude that, within the multi-layer scheme of internal claim review administered by the Secretary, the early stage of ALJ review is the

[5] *Christenson* is similarly an appeal of the denial of coverage for the Optune device.

[6] The Supreme Court "regularly turns to the Restatement (Second) of Judgments for a statement of the ordinary elements of issue preclusion." *B & B Hardware, Inc. v. Hargis Industries, Inc.*, 575 U.S. 138, 148 (2015).

point at which an issue becomes final for purposes of collateral estoppel.").[7]

Given these considerations, it is no surprise that the Fifth Circuit and other circuit courts have unanimously acknowledged that in Medicare claim appeals, ALJ decisions have no preclusive effect. *W. Texas LTC Partners, Inc. v. Dep't of Health & Human Servs.*, 843 F.3d 1043, 1047 (5th Cir. 2016) ("[P]rior ALJ decisions are not binding on the DAB or other ALJs."); *Almy,* 679 F.3d at 310-11 (only Council-level decisions constitute the final decision of the Secretary; plaintiff's proposed expansion of what constitutes binding precedent would severely constrict administration of the Medicare program; lower-level decisions cannot bind the Secretary just as lower courts cannot bind the Supreme Court); *Porzecanski*, 943 F.3d at 477 ("[A] favorable determination in one proceeding does not ensure that future claims will be approved."); *Taransky v. Secretary of U.S. Dept. of Health and Human Services*, 760 F.3d 307, 319 (3rd Cir. 2014) (Council owes no deference to and is not bound by ALJs); *Int'l Rehab. Sci. Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) (adopting reasoning in *Almy*).[8]

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[7] Plaintiff's citations in support of the proposition that ALJ decisions are final, Docket 60, p. 19, are inapposite. First, 70 Fed.Reg. 36386-7 (June 23, 2005) is merely a statement of organization for the Office of Medicare Hearings and Appeals. In contrast, 42 C.F.R. § 405.1048 specifically addresses the effect of an ALJ's decision. Second, while *Smith v. Berryhill*, 139 S. Ct. 1765, 1775-76 (2019) addresses finality for purposes of appeal to federal court, it does not address finality for purposes of issue preclusion.

[8] Plaintiff's citations for the proposition that agency determinations can have preclusive effect, Docket 60, pp. 5-6, are not on point because none involve an ALJ decision in the Medicare claim appeals context. The only case that implicates Medicare at all, *DeWall Enterprises, Inc. v. Thompson*, 206 F. Supp. 2d 992 (D. Neb. 2002), involved a dispute over the proper coding for an orthotics device. After four ALJs found that the code used by DeWall was appropriate (and none of those decisions were appealed), a Medicare contractor informed DeWall that the code used by DeWall was inappropriate. In rejecting the Secretary's argument that the Secretary was free to interpret the code differently because ALJ decisions are not precedential, the Court wrote: "[t]he Secretary's assertions that the ALJ's decisions are not afforded any preclusive effect are without merit." *Id.* at 1001. In this context, the Court simply meant that the Secretary was required to implement the un-appealed ALJ decisions. *DeWall* did not address whether an ALJ decision adjudicating the "reasonable and necessary" standard could have preclusive effect on a subsequent ALJ decision.

In sum, the Medicare Act: (1) requires *de novo* review of ALJ decisions, (2) affords the Secretary the right to implement the "reasonable and necessary" standard through individual adjudication, (3) requires claims for benefits to be presented and channeled through administrative review, and (4) authorizes regulations, which foreclose giving preclusive effect to ALJ decisions. As recognized by courts in the Fifth, Third, Fourth, Seventh, Ninth, and DC circuits, all of these aspects of the Medicare Act are incompatible with giving preclusive effect to ALJ decisions in the context of Medicare claim appeals. The Medicare Act therefore evidences a statutory purpose to the contrary, so the Secretary cannot be collaterally estopped in this case.[9] *Cf. Christenson*, 2020 WL 3642315, at *4-7 (E.D. Wis. Jul. 6, 2020) (Medicare's administrative review structure was incompatible with applying collateral estoppel on the basis of ALJ-level decisions).

B. Even If Collateral Estoppel Were Possible, the Elements are Not Met

Even if ALJ decisions in the Medicare claim appeals context were capable of having preclusive effect, Plaintiff's request to estop the Secretary from denying coverage in this case would still fail because the elements of collateral estoppel are not met. When collateral estoppel is possible, it applies only when:

> (1) the issue at stake is identical to the one involved in the prior proceeding;
> (2) the issue was actually litigated in the prior proceeding;
> (3) the determination of the issue in the prior litigation must have been "a critical and necessary part" of the judgment in the first action; and
> (4) the party against whom collateral estoppel is asserted must have had a full and fair opportunity to litigate the issue in the prior proceeding.

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[9] To the extent Plaintiff's request to collaterally estop the Secretary is grounded in concerns about the need to re-litigate whether the provision of TTFT through the Optune device is a covered Medicare benefit, Plaintiff could have used separate channels of review to challenge the applicable LCD for TTFT or to petition CMS for an NCD. 42 U.S.C. § 1395y(1) (describing process of requesting an NCD); 42 C.F.R. Part 426, Subpart D (describing process for challenging an LCD).

Wehling v. CBS, 721 F.2d 506, 508 (5th Cir. 1983).[10] Plaintiff cannot carry his burden on the first, second, and fourth elements of collateral estoppel.

As discussed in the Secretary's principal brief, the issue at stake in this case -- whether the Medicare Appeals Council properly denied coverage for TTFT for the months of April 19, 2018 through June 19, 2018 -- is not identical to the issue in the earlier ALJ proceedings and the issue was not actually litigated in the prior proceedings. Docket 58, pp. 16-17. Each decision concerned whether TTFT was covered under Medicare for a *specific period in time*. Docket 60, p. 17. The issue here is not whether Plaintiff's condition changed on a month-to-month basis; it is instead that the ALJ rulings were expressly limited to certain time period; they never adjudicated whether coverage existed at other time periods; and they lacked authority to determine that coverage existed for future claims.

Plaintiff asserts that the Secretary had a full and fair opportunity to litigate in the earlier ALJ proceedings because counsel for the Secretary had the right to appear, even though counsel did not in fact appear. Pl. Br. at 20; 42 C.F.R. § 405.1012 (Secretary permitted to appear at ALJ hearings when beneficiary is represented by counsel). However, Plaintiff ignores that there are thousands of ALJ appeals filed each year and the Secretary cannot possibly appear in every one. 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting 650,000 pending ALJ appeals as of September 2016). Given the practical impossibility for the Secretary to appear in every ALJ appeal, the Secretary only has a full

[10] Plaintiff contends that the Fifth Circuit does not apply the fourth factor, whether "the party against whom collateral estoppel must have had a full and fair opportunity to litigate the issue in the prior proceeding." The Fifth Circuit has, however, applied this fourth element when determining whether collateral estoppel applies. *Wehling v. CBS*, 721 F.2d 506, 508 (5th Cir. 1983); *Rabo Agrifinance, Inc. v. Terra XXI*, 583 F.3d 348, 353 (5th Cir. 2009).

and fair opportunity to litigate if he actually appears—which in this case, he did not. Plaintiff therefore cannot establish the fourth element of collateral estoppel.

Plaintiff relies on data that the Secretary produced in response to Plaintiff's Interrogatories to further his argument that the Secretary had a fair opportunity to litigate in the earlier ALJ proceedings. Docket 60, pp. 20-21. The data concern the number of requests for ALJ hearings in Medicare claim appeals for fiscal years 2018 and 2019. The data are segregated by whether the hearing was requested by the Medicare beneficiary or by a non-beneficiary (e.g., the provider or supplier of services), and whether the requesting party had representation at the time the request was docketed. Plaintiff requested this data with the goal of refuting the Secretary's argument that it is practically impossible for him to litigate in every ALJ hearing where he is eligible to appear. Docket 50. However, the data in fact support the Secretary's position.[11]

Under 42 C.F.R. § 405.1012(a)(1), Defendant is entitled to appear at an ALJ hearing for a Medicare claim appeal "unless the request for hearing is filed by an unrepresented beneficiary." Thus, the Secretary is eligible to appear at all ALJ hearings when the request was filed by a represented beneficiary, and also at all ALJ hearings when the request was filed by a non-beneficiary (regardless of representation status). Given this legal background, the relevant data disclosed to Plaintiff are as follows:

	Fiscal Year 2018	Fiscal Year 2019
Represented Beneficiary ALJ Requests	2,062	2,602
Non-Beneficiary ALJ Requests	56,497	37,022
Total Number of ALJ Requests	62,762	43,887

Docket 60-2.

[11] Plaintiff characterizes the Secretary as being resistant to disclose the data because it would harm his case. Docket 60, p. 21. To the contrary, the Secretary's position is that the Court's review is limited to the certified Administrative Record. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

These data show that the Secretary was eligible to appear in 58,559 of the ALJ hearings requested in fiscal year 2018 and 39,624 of the ALJ hearings requested in fiscal year 2019.[12] Plaintiff contends that some of these hearing requests were dismissed. Even if we reduce these numbers by the percentage of appeals that were dismissed (the overall dismissal rate was 60.7% in fiscal year 2018 and 54.3% in fiscal year 2019),[13] the Secretary was still eligible to appear in 23,014 of the ALJ hearings requested in fiscal year 2018 and 18,108 of the ALJ hearings requested in fiscal year 2019.

Moreover, the number of ALJ hearings requested by represented beneficiaries and by non-beneficiaries in fiscal years 2018 and 2019 is not the full story. There is also a significant backlog of ALJ hearing requests from earlier fiscal years. *Am. Hosp. Assoc. v. Azar*, 14-cv-851, Dkt. No. 98 (D.D.C. Jun. 26, 2020 Status Report) (showing beginning workload balance of 578,683 ALJ hearings in fiscal year 2018 and 417,198 ALJ hearings in fiscal year 2019). The Secretary is likely eligible to appear (and has been eligible to appear) in hundreds of thousands of these backlogged hearing requests.

In sum, the data show that it is practically impossible for the Secretary to participate in all of the ALJ hearings where he is eligible to appear.[14] *Christenson v. Azar*,

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[12] Plaintiff's Brief cherry-picks the data by focusing on the number of hearings requested by represented beneficiaries, completely ignoring that the Secretary is eligible to appear in all hearings requested by non-beneficiaries. Docket 60, pp. 21-22. For purposes of assessing whether an ALJ decision has preclusive effect, there is no principled distinction between hearings requested by beneficiaries versus non-beneficiaries.

[13] HHS.gov, *Decision Statistics*, available at https://www.hhs.gov/about/agencies/omha/about/current-workload/decision-statistics/index.html (Aug. 21, 2020). Notably, the published data does not specify whether dismissals occurred prior to hearing (*i.e.*, before Defendant would have had an opportunity to appear) or whether the dismissal rate was consistent across different categories of appeal (*e.g.*, unrepresented beneficiary versus represented beneficiary versus non-beneficiary, etc.).

[14] The Secretary also notes that its counsel has numerous responsibilities apart from Medicare litigation. 85 Fed. Reg. 54581 – 54856 (Sept. 2, 2020) (Statement of Organization for Defendant's Office of General Counsel). Accordingly, Plaintiff speculates about the Secretary's capacity to litigate

No. 20-cv-194, 2020 WL 3642315, at *7 (E.D. Wis. Jul. 6, 2020), *reconsideration denied sub nom. Prosser v. Azar,* 2020 WL 6266051 (Sept. 24, 2020), *appeal docketed*, No. 20-3070 (7th Cir. Oct. 22, 2020) ("even several thousand beneficiary appeals filed annually makes it virtually impossible for the Secretary to be represented at every ALJ-level hearing.").

Plaintiff relies on the Supreme Court's decision in *United States v. Mendoza* for the proposition that the number of ALJ appeals is irrelevant to the issue before this Court. Docket 60, p. 20; 464 U.S. 154, 159-60 (1984). In *Mendoza*, the Court held that non-mutual collateral estoppel did not apply against the federal government. *Id.* at 162. The Court cited to the number of district court cases where the United States was a party, 75,000, merely in dicta. *Id.* at 159-160. Moreover, the number cited by the Court applied to the federal government across all agencies, not one agency. *Id.* at 160.

Even if ALJ decisions in the Medicare claim appeals context were capable of having preclusive effect, the ALJ decisions relied upon by Plaintiff in this case would not qualify because the Secretary lacked a full and fair opportunity to litigate in those proceedings. This is further reason why the Secretary is not collaterally estopped from denying coverage in this case.[15]

Conclusion

ALJ decisions in the Medicare claim appeals context are not capable of having preclusive effect, and even if they were, the elements for collateral estoppel are not met in

several thousand ALJ hearings based on the productivity of his private counsel's firm. Docket 60, p. 22, fn 15.

[15] Even if the ALJ decisions were entitled to preclusive effect, due to the revised LCD for TTFT, Plaintiff would only be able to rely upon it for claims for the Optune device with dates of service before September 1, 2019. *See Montana v. United States*, 440 U.S. 147, 155 (1979) (collateral estoppel will not apply when "controlling facts or legal principles have changed significantly since the [prior] judgment.").

this case. For the foregoing reasons, and for those set out in the Secretary's principal brief, the Court should affirm the final agency decision of the Secretary, and Plaintiff's motion should be denied.

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